

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re: Stephen Griffin et al. Confirmation No.: 1334
Serial No.: 10/729,742 Examiner: Jeffrey G. Hoekstra
Filing Date: December 5, 2003 Group Art Unit: 3736
Docket No.: 1001.1727101 Customer No.: 28075
For: GUIDE CATHETER WITH REMOVABLE SUPPORT

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Commissioner for Patents
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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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By



Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellants hereby submit this Appeal Brief in furtherance of the Notice of Appeal filed on November 16, 2007 and of the Notices of Panel Decision from Pre-Appeal Review dated January 8, 2008 and January 16, 2008. Applicants authorize the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of \$510.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Boston Scientific Scimed, Inc., a corporation organized and existing under the laws of the State of Minnesota, and having its principal offices at One Scimed Place, Maple Grove, Minnesota, 55311-1566. An assignment from inventors Stephen Griffin and Gregory E. Mirigian conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 014780, Frame 0326; and a change of name from SciMed Life Systems, Inc. to Boston Scientific Scimed, Inc. has been recorded at Reel 018505, Frame 0868.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-9 and 11-21 are pending in the application, wherein claim 8 has been withdrawn from consideration. Claims 10 and 22-25 have been cancelled from the application.

Claims 1-7, 9, 14-15, 18 and 21 stand rejected under 35 U.S.C. §102(e) as being anticipated by Furnish (U.S. Patent No. 6,873,868).

Claims 11-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Furnish (U.S. Patent No. 6,873,868) in view of Rammler (U.S. Patent No. 5,327, 891).

Claims 16 and 17 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Furnish (U.S. Patent No. 6,873,868) in view of MacDonald et al. (U.S. Patent No. 6,210,396).

Claims 19 and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Furnish (U.S. Patent No. 6,873,868) in view of Rammler (U.S. Patent No. 5,327, 891).

The rejection of claims 1-7, 9 and 11-21 of the application is currently being appealed.

IV. STATUS OF AMENDMENTS

No amendments were filed subsequent to final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER¹

The invention pertains to catheters that are configured for device delivery while retaining a desired level of flexibility (see specification, page 1, line 30 through page 2, line 4). In particular, the invention is directed to catheters that provide a desired level of flexibility for advancing the catheter into a patient's vasculature yet can be provided with sufficient column support once the catheter has reached a desired position within the vasculature. If desired, the column support can be removed prior to removal of the catheter. Please see page 2, lines 5-17 of the instant specification.

Turning now to the claims, claim 1 is directed to a catheter (reference character 10, Figure 1) that includes an elongate shaft (page 4, line 30; reference character 12, Figure 1) and removable support means for providing column support to the elongate shaft (reference character 12). Structures described in the specification as possibly being the claimed removable support means may be considered as including the support ribs (page 9, lines 12-18; reference character 46, Figure 8) and the support sheath (page 11, lines 3-10; reference character 47, Figure 12).

The elongate shaft (reference character 12) may be considered as including a proximal region (reference character 14, Figure 1), a distal region (reference character 16, Figure 1) and an exterior surface (shown in Figure 1) that extends between the proximal and distal regions (reference characters 14, 16). See page 4, line 30 of the instant specification. The removable support means (reference characters 46, 47) are disposed over at least a portion of the exterior surface of the elongate shaft (reference character 12) (page 2, lines 8-9).

¹ The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting.

Claim 2 depends from claim 1, and adds anchoring means for securing the removable support means (reference characters 46, 47). Structures described in the specification as possibly being the claimed anchoring means may be considered as including the elongate tracks (page 7, lines 8-16; reference character 34, Figures 3, 4, 6, 7, 10 and 11; page 8, line 25 through page 9, line 2), reference character 44, Figures 5 and 12). The anchoring means (reference character 34) are disposed on a portion of the exterior surface of the elongate shaft (reference character 12). Claim 3 depends from claim 2, and recites that the anchoring means (reference characters 34, 44) have a cross-sectional profile that is configured to permit the removable support means (reference characters 46, 47) to move axially with respect to the elongate shaft (reference character 12) while limiting relative radial movement. See page 9, lines 12-18 of the specification. This is illustrated, for example, in Figures 10 and 11.

Claim 9 is an independent claim pertaining to a modular guide catheter (page 2, lines 10-17 as well as reference character 10, Figure 1) that includes an elongate shaft (reference character 12) having a proximal region (reference character 14), a distal region (reference character 16) and a lumen (page 5, line 10; reference character 32, Figures 2, 4, 6, 7 and 11; page 8, lines 25-26; reference character 40, Figures 5 and 11) that extends between the proximal and distal regions. The elongate shaft includes an external surface as shown in the Figures. A plurality of support tracks (page 7, lines 9-15; reference character 34) are disposed on the external surface of the elongate shaft and are axially aligned with the elongate shaft. A plurality of support ribs (page 9, lines 12-18, reference character 46) are configured to be removably disposed over at least a portion of the plurality of support tracks. Each of the support tracks have a cross-sectional profile that is configured to permit each of the support ribs to move axially with

respect to each support track (while limiting relative radial movement. Please see page 9, lines 12-18 of the instant specification. This can be seen, for example, in Figures 10 and 11.

Claim 11 depends from claim 10, and specifies that the cross-sectional profile of each support track (reference character 34) has an ovoid cross-section having a minor dimension (reference d1 in Figure 9) that is perpendicular to the exterior surface of the elongate surface and a major dimension (reference d2 in Figure 9) that is perpendicular to the minor dimension (see page 9, lines 20-27 of the instant specification). Claim 16 depends from claim 9 and specifies that the plurality of support tracks (reference character 34) are heat bonded (page 8, lines 20-21) to the exterior surface of the elongate shaft (reference character 12).

Claim 19 depends from claim 9 and recites that each of the plurality of support ribs (reference character 46) comprises a fluorinated polyethylene polymer. Claim 20 depends from claim 19 and specifies that the fluorinated polyethylene polymer is polytetrafluoroethylene (page 10, lines 3-6).

VI. GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

1. Whether claims 1-7, 9, 14-15, 18 and 21 are anticipated under 35 U.S.C. §102(e) by Furnish (U.S. Patent No. 6,873,868).
2. Whether claims 11-13 are unpatentable under 35 U.S.C. §103(a) over Furnish (U.S. Patent No. 6,873,868) in view of Rammler (U.S. Patent No. 5,327,891).
3. Whether claims 16-17 are unpatentable under 35 U.S.C. §103(a) over Furnish (U.S. Patent No. 6,873,868) in view of MacDonald et al. (U.S. Patent No. 6,210,396).
4. Whether claims 19-20 are unpatentable under 35 U.S.C. §103(a) over Furnish (U.S. Patent No. 6,873,868) in view of Rammler (U.S. Patent No. 5,327,891).

VII. ARGUMENT

A. CLAIMS 1-7, 9, 14-15, 18 and 21 ARE NOT ANTICIPATED BY FURNISH (U.S. PATENT NO. 6,873,868) UNDER 35 U.S.C. § 102(e).

It is noted that independent claim 1 recites “removable support means for providing column support to the elongate shaft.” In examining claim limitations evoking a mean-plus-function evaluation, a two-step process must be conducted. First, the element found in the prior art must perform the same function specified in the claim. Second, the structure of the prior art element must be found to perform the function in substantially the same way while producing substantially the same results as the corresponding element disclosed in the specification. See M.P.E.P. §§2181-2184. The Examiner has repeatedly ignored these requirements, asserting instead that independent claim 1 is not entitled to a means-plus-function interpretation. This is an error made by the Examiner.

In maintaining this anticipation rejection, the Examiner has asserted (see paragraph 11 of the Final Office Action mailed September 17, 2007) that the pending claims are not entitled to means-plus-function consideration under 35 U.S.C. §112, 6th paragraph. As discussed in the Conference Brief filed November 16, 2007, the Examiner has asserted that claim 1 is not entitled to a means-plus-function interpretation because the “removable support means for providing column support to the elongate shaft” are referred to in subsequent claims as “the removable support means” and because the “anchoring means for securing the removable support means” are referred to in subsequent claims as “the anchoring means”. Appellants believe that the claims as pending properly employ means-plus-function terminology and thus appropriately invoke 35 U.S.C. §112, 6th paragraph. Therefore, the Examiner has no appropriate or reasonable basis for not examining the pending claims under the requirements of 35 U.S.C. §112, 6th

paragraph. Thus, the Examiner has made an error in not evaluating these claims using the two-step process noted above.

In particular, the Examiner is equating the signal fiber 130 to the removable support means of claim 1. In view of the requirements of showing equivalence of a means-plus-function limitation, Appellants respectfully disagree with this suggestion of equivalence. In order to show equivalence, it must first be demonstrated that the signal fiber 130 of Furnish performs the same function as the claimed limitation. Appellants respectfully assert that the signal fiber of Furnish does not meet the functional requirements of a “removable support means for providing column support to the elongate shaft.”

Signal fiber 130 of Furnish is disclosed as a signal fiber for delivering or receiving beams of light energy. Furnish at column 10, lines 9-11. At no point does Furnish suggest that signal fiber 130 performs the function of a removable support means for providing column support to the elongate shaft. The mere addition of material does not imply that column support is increased. For example, the mass of the shaft may remove or overshadow any stiffness that the signal fiber may provide to the catheter.

Moreover, the signal fiber of Furnish is not an equivalent structure which performs the function in substantially the same way while producing substantially the same results as the corresponding element disclosed in the instant specification. The signal fiber of Furnish, to the extent it functions as a support means, if at all, does so by being captured between the catheter and a sheath. As can be seen in Figure 1A, for example, the walls of the groove are parallel and therefore the groove by itself does not retain the signal fiber. In contrast, the removable support means taught in the specification of the present application provide additional column support by removably attaching to the elongate shaft exterior surface in a manner which limits the radial

movement of the support means with respect to the catheter without the use of an additional sheath. Therefore, the signal fiber of Furnish does not provide column support in substantially the same way as the removable support means of claim 1.

For at least the reasons stated above, the teachings of Furnish at least fail to teach “removable support means for providing column support to the elongate shaft” as currently claimed. Claim 1, as well as claims 2-7 which depend from claim 1 and include additional significant limitations, are believed to be in condition for allowance. Favorable reconsideration is respectfully requested.

Further, claim 2 recites “anchoring means for securing the removable support means.” The Examiner is equating alignment groove 124 with the anchoring means of claim 2. Appellants respectfully disagree with this suggestion of equivalence. In order to show equivalence, it must first be demonstrated that the alignment groove 124 of Furnish performs the same function as the claimed limitation. Appellants respectfully assert that the alignment groove 124 of Furnish does not meet the functional requirements of an “anchoring means for securing the removable support means.”

According to Furnish, alignment grooves 124 are used to carry signal fibers 130. Furnish at column 10, line 5. At no point does Furnish suggest that alignment groove 124 performs the function of securing the removable support means. On the contrary, Furnish shows the signal fibers captured between the catheter and a sheath. The catheter grooves, which have parallel sides as can be seen in Figure 1A, are unable by themselves to secure the signal fibers. It can therefore be seen that the alignments grooves of Furnish do not perform substantially the same function as the anchoring means of claim 2. It is therefore unnecessary to perform the second step of the means-plus-function evaluation.

Further, claim 3 recites “wherein the anchoring means have a cross-sectional profile configured to permit the removable support means to move axially with respect to the elongate shaft while limiting relative radial movement.” The Examiner argues that Furnish, in column 8, lines 33-37, teaches such a configuration. However, Furnish merely teaches that each signal fiber “may be longitudinally displaceable within their respective alignment grooves.” Furnish at column 8, lines 34-36. Furnish does not specifically say that the alignment grooves limit relative radial movement. To the contrary, Furnish teaches that “the housing has an outer peripheral surface having a plurality of spaced apart, *parallel*, longitudinally directed alignment grooves thereon.” Furnish at column 1, lines 64-66 (*italics added*). As can be seen in Figure 1, for example, the sides of each alignment groove are parallel, and therefore the alignment grooves are unable to prevent the radial movement outwards of the signal fibers. An additional sheath, as shown in Figure 7, keeps the signal fibers in their alignment grooves.

For the reasons discussed above with respect to claim 1 and these additional reasons, Appellants respectfully submit that claims 2 and 3 and claims 4-7 which depend therefrom are in condition for allowance.

With respect to claim 9, Applicants note that the claim requires that each of the support tracks have a cross-sectional profile configured to permit each of the support ribs to move axially with respect to each support track while limiting relative radial movement. Furnish does not disclose this, despite the Examiner’s assertions to the contrary.

At page 7 of the Final Office Action mailed September 17, 2007, the Examiner has asserted that “Furnish shows support tracks having a complementary cross-sectional profile to the support means, said cross-sectional profile capable of permitting the removable support means to move axially with respect to the elongate shaft while limiting relative radial

movement.” This is incorrect. The alignment grooves disclosed by Furnish may limit relative circumferential movement. The alignment grooves are not appropriately configured and thus cannot reasonably be considered as limiting (or being capable of limiting) relative radial movement. This is a claimed feature expressly missing from the cited reference.

Moreover, it is noted that claim 9 recites “a plurality of support tracks disposed on the external surface of the elongate shaft”. Appellants do not believe that an alignment groove formed within an outer surface of a shaft is equivalent to a support track that is disposed on the shaft. Claim 9 also recites “a plurality of support ribs that are configured to be removable disposed over at least a portion of the plurality of support tracks”. Appellants do not believe that a signal fiber extending within an alignment groove qualifies as a support rib that is disposed over at least a portion of a support track. In any event, Appellants do not concede that a signal fiber qualifies as a support rib.

For at least these reasons, Appellants respectfully submit that claim 9 is in condition for allowance. As claims 14-15, 18 and 21 depend therefrom and contain additional elements, Appellants submit that these claims are in condition for allowance as well. Favorable reconsideration is respectfully requested.

B. CLAIMS 11-13 ARE PATENTABLE OVER FURNISH (U.S. PATENT NO. 6,873,868) IN VIEW OF RAMMLER (U.S. PATENT NO. 5,327,891) UNDER 35 U.S.C. § 103(a).

Claim 9, from which claims 11-13 depend and further limit, is distinguished above as being patentable over Furnish. Rammler is not believed to remedy the noted shortcomings of Furnish, and thus claim 9 is similarly patentable over the asserted combination of Furnish in view of Rammler. Claims 11-13 include the elements of claim 9, and thus are patentable for at least the same reasons.

Moreover, and with respect to claim 11, Appellants note that claim 11 recites “wherein the cross-section profile comprises an ovoid cross-section.” The Examiner argues that tracks 82 and 94 comprise an ovoid cross section. However these cross sections, which have four sharp corners, are not ovoid. Moreover, the elements 82 and 94 of Rammler, as can be seen in Figure 4, do not limit relative radial movement between, for example, element 82 and element 86. Element 82 is small enough that it can move in and out of the groove in element 86. It can therefore be seen that Furnish in view of Rammler does not disclose each and every element claimed in claim 11. Favorable reconsideration is respectfully requested.

C. CLAIMS 16-17 ARE PATENTABLE OVER FURNISH (U.S. PATENT NO. 6,873,868) IN VIEW OF MACDONALD ET AL. (U.S. PATENT NO. 6,210,396) UNDER 35 U.S.C. § 103(a).

Claim 9, from which claims 16-17 depend and further limit, is distinguished above as being patentable over Furnish. MacDonald et al. are not believed to remedy the noted shortcomings of Furnish, and thus claim 9 is similarly patentable over the asserted combination of Furnish in view of MacDonald et al. Claims 16-17 include the elements of claim 9, and thus are patentable for at least the same reasons.

Moreover, and with respect to claim 16, Appellants note that the Examiner argues at pages 4 and 5 in the Final Office Action that “Furnish discloses the claimed invention except for explicitly disclosing attaching a portion of a catheter device by heat bonding or adhesives. MacDonald teaches attaching a portion of the catheter by using either heat bonding or adhesives.” However, the Examiner previously argued that the plurality of tracks claimed in claim 9 were anticipated by the alignment grooves of Furnish; but claim 16, for example, recites “wherein the plurality of support grooves are heat bonded to the exterior surface of the elongate shaft.” One cannot attach grooves to a catheter by heat bonding or adhesives because grooves

are formed by removing material (or not applying material originally) and are not formed by adding material. Because grooves are not formed by heat bonding or by the use of adhesives, there is no reasonable chance of success, and thus no *prima facie* case of obviousness has been made. For this reason, and for the reason that claims 16-17 depend from claim 9, which Appellants submit is allowable, and contain additional elements, favorable reconsideration is respectfully requested.

D. CLAIMS 19-20 ARE PATENTABLE OVER FURNISH (U.S. PATENT NO. 6,873,868) IN VIEW OF RAMMLER (U.S. PATENT NO. 5,327,891) UNDER 35 U.S.C. § 103(a).

Claim 9, from which claims 19-20 depend and further limit, is distinguished above as being patentable over Furnish. Rammler is not believed to remedy the noted shortcomings of Furnish, and thus claim 9 is similarly patentable over the asserted combination of Furnish in view of Rammler. Claims 19-20 include the elements of claim 9, and thus are patentable for at least the same reasons.

Moreover, with respect to claims 19 and 20, the Examiner argues that “Furnish discloses the claimed invention except for explicitly disclosing the plurality of support ribs comprising a fluorinated polyethylene polymer and specifically polytetrafluoroethylene” and that Rammler supplies this deficiency. However, the signal fibers of Furnish, which the Examiner has held anticipates the claimed support ribs, must transmit energy and specifically light energy from one end to the other. If the substituted material does not effectively transmit light energy, the proposed modification would make the apparatus unsuitable for its intended use. Polytetrafluoroethylene is generally opaque, which suggests that it and other fluorinated polyethers would be unsuitable for use as the signal fibers of Furnish. For this reason, there is no motivation to combine the references, and a *prima facie* case of obviousness has not been made.

For this reason and for the reason that claims 19-20 depend from claim 9, which Appellants submit is allowable, and contain additional elements, favorable reconsideration is respectfully requested.

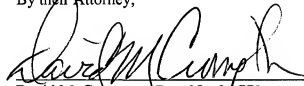
VIII. CONCLUSION

For the reasons stated above, claims 1-7, 9, 14-15, 18 and 21 are not anticipated by Furnish under 35 U.S.C. § 102(e); claims 11-13 are patentable over Furnish in view of Rammler under 35 U.S.C. § 103(a); claims 16-17 are patentable over Furnish in view of MacDonald et al. under 35 U.S.C. § 103(a); and claims 19-20 are patentable over Furnish in view of Rammler under 35 U.S.C. § 103(a). The Examiner's rejections of claims 1-7, 9, and 11-21 should be overruled.

Respectfully submitted,

Stephen Griffin et al.

By their Attorney,

A handwritten signature in black ink, appearing to read "David M. Crompton", is written over a horizontal line.

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2/13/08

IX. CLAIMS APPENDIX

1. A catheter comprising:

an elongate shaft having a proximal region, a distal region, and an exterior surface extending therebetween; and

removable support means for providing column support to the elongate shaft, the removable support means disposed over at least a portion of the exterior surface of the elongate shaft.

2. The catheter of claim 1, further comprising anchoring means for securing the removable support means, the anchoring means disposed on a portion of the exterior surface of the elongate shaft.

3. The catheter of claim 2, wherein the anchoring means have a cross-sectional profile configured to permit the removable support means to move axially with respect to the elongate shaft while limiting relative radial movement.

4. The catheter of claim 2, wherein the anchoring means comprises one or more support tracks axially disposed on the exterior surface of the elongate shaft.

5. The catheter of claim 4, wherein the removable support means comprises one or more support ribs configured to be disposed over the one or more support tracks.

6. The catheter of claim 5, wherein each of the one or more support ribs slide axially over each of the one or more support tracks.

7. The catheter of claim 4, wherein the one or more support tracks comprise four support tracks that are axially disposed such that each support is radially evenly spaced around the elongate shaft.

9. A modular guide catheter, comprising:

an elongate shaft having a proximal region, a distal region and a lumen extending therebetween, the elongate shaft having an external surface;

a plurality of support tracks disposed on the external surface of the elongate shaft, the support tracks axially aligned with the elongate shaft; and

a plurality of support ribs that are configured to be removably disposed over at least a portion of the plurality of support tracks,

wherein each of the support tracks have a cross-section profile configured to permit each of the support ribs to move axially with respect to each support track while limiting relative radial movement.

11. The modular guide catheter of claim 9, wherein the cross-section profile comprises an ovoid cross-section having a minor dimension perpendicular to the exterior surface of the elongate surface and a major dimension perpendicular to the minor dimension.

12. The modular guide catheter of claim 11, wherein the major dimension varies as a function of distance from the exterior surface of the elongate shaft.

13. The modular guide catheter of claim 11, wherein the major dimension is minimized at a position proximate the exterior surface of the elongate shaft and is maximized at a position radially displaced from the exterior surface a distance equal to or less than the minor dimension.

14. The modular guide catheter of claim 9, wherein each of the plurality of support ribs have a cross-section profile complementary to the cross-section profile of each of the plurality of support tracks.

15. The modular guide catheter of claim 9, wherein the plurality of support tracks comprise four support tracks axially aligned along the elongate shaft, each equidistantly spaced around a radius of the elongate shaft.

16. The modular guide catheter of claim 9, wherein the plurality of support tracks are heat bonded to the exterior surface of the elongate shaft.

17. The modular guide catheter of claim 9, wherein the plurality of support tracks are adhesively secured to the exterior surface of the elongate shaft.

18. The modular guide catheter of claim 9, wherein the plurality of support tracks are integrally extruded with the elongate shaft.

19. The modular guide catheter of claim 9, wherein each of the plurality of support ribs comprises a fluorinated polyethylene polymer.

20. The modular guide catheter of claim 19, wherein the fluorinated polyethylene polymer comprises polytetrafluoroethylene.

21. The modular guide catheter of claim 9, wherein the distal region of the elongate shaft includes a distal end, and the plurality of support tracks extend from a position proximate the proximal region of the elongate shaft to a position proximal of the distal end of the elongate shaft.

X. EVIDENCE APPENDIX

No additional evidence has been presented.

XI. RELATED PROCEEDINGS APPENDIX

none